DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 177

[Docket No. 96F–0107]

Indirect Food Additives: Polymers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of a polyester-polyurethane resin-acid dianhydride adhesive in retortable pouches intended for use in contact with food.

DATES: The regulation is effective (*insert date of publication in the* **Federal Register**). Submit written objections and requests for a hearing by (*insert date 30 days after date of publication in the* **Federal Register**).

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Mark A. Hepp, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3098.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of April 23, 1996 (61 FR 17901), FDA announced that a food additive petition (FAP 6B4496) had been filed by Dainippon Ink and Chemicals, Inc., c/o Center for Regulatory Services, 2347 Paddock Lane, Reston, VA 22091. The petition proposed to amend the food additive regulations in § 177.1390 *Laminate structures for use at temperatures of 250* °F *and above* (21 CFR 177.1390) to permit

the safe use of aliphatic polyester-polyurethane resin-acid dianhydride adhesive in retortable pouches intended for use in contact with food.

When the petition was filed, it contained an environmental assessment (EA). In the notice of filing (61 FR 17901), the agency announced that it was placing the EA on display at the Dockets Management Branch (address above) for public review and comment. No comments were received. In the **Federal Register** of July 29, 1997 (62 FR 40570), FDA published a document that revised regulations under part 25 (21 CFR part 25), which became effective on August 28, 1997. On March 24, 1998, the petitioner made a claim of categorical exclusion under the new paragraph in § 25.32(i), in accordance with the procedures in § 25.15(a) and (d). Because the agency had not completed its review of the earlier submitted EA, the agency reviewed the claim of categorical exclusion under § 25.32(i) for this final rule.

The additive was identified in the filing notice as an aliphatic polyester-polyurethane resin-acid dianhydride adhesive. It is unclear to which structural unit the term aliphatic applies, and moreover, such distinction is not necessary to adequately identify the chemical composition of the additive. Therefore, the additive will be listed as a polyester-polyurethane resin-acid dianhydride adhesive in this final rule.

FDA has evaluated data in the petition and other relevant material. Based on this information, the agency concludes that: (1) The proposed use of the additive is safe, (2) the additive will achieve its intended technical effect, and therefore, (3) the regulations in § 177.1390 should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has determined under § 25.32(i) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an EA nor an environmental impact statement is required.

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

Any person who will be adversely affected by this regulation may at any time on or before (*insert date 30 days after date of publication in the* **Federal Register**), file with the Dockets Management Branch (address above) written objection thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objection received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 177

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 177 is amended as follows:

PART 177—INDIRECT FOOD ADDITIVES: POLYMERS

1. The authority citation for 21 CFR part 177 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 379e.

2. Section 177.1390 is amended by adding paragraph (c)(2)(vii) and by revising paragraph (c)(3)(i)(*a*)(*1*) to read as follows:

§ 177.1390 Laminate structures for use at temperatures of 250 °F and above.

* * * * *

(c) * * *

(2) * * *

(vii) Polyester-polyurethane resin-acid dianhydride adhesives for use at temperatures not to exceed 121 °C (250 °F), in contact only with food Types I, II, VIA, VIB, VIIB, and VIII as described in Table I of § 176.170 of this chapter, and formulated from the following mixture:

(*a*)(*1*) Polyesterpolyurethanediol resins prepared by the reaction of a mixture of polybasic acids and polyhydric alcohols listed in § 175.300(b)(3)(vii) of this chapter and 3-isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate (CAS Reg. No. 4098–71–9). Additionally, dimethylol propionic acid and 1,6-hexanediol may be used alone or in combination as reactants in lieu of a polybasic acid and a polyhydric alcohol.

(*2*) Acid dianhydride formulated from 3a,4,5,7a-tetrahydro-7-methyl-5-(tetrahydro-2,5-dioxo-3-furanyl)-1,3-isobenzofurandione (CAS Reg. No. 73003–90–4), comprising not more than one percent of the cured adhesive.

(*b*) Urethane cross-linking agent, comprising not more than twelve percent by weight of the cured adhesive, and formulated from trimethylol propane (CAS Reg. No. 77–99–6) adducts of 3-isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate (CAS Reg. No. 4098–71–9) and/or 1,3-bis(isocyanatomethyl)benzene (CAS Reg. No. 363–48–31).

(3) * * *

(i) * * *

(*a*) * * *

(*1*) The chloroform-soluble fraction of the total nonvolatile extractives for containers using adhesives listed in paragraphs (c)(2)(i), (c)(2)(ii), (c)(2)(iii), (c)(2)(iv), and (c)(2)(vii) of this section shall not exceed 0.0016 milligram per square centimeter (0.01 milligram per square inch) as determined by a method entitled ''Determination of Non-Volatile Chloroform Soluble Residues in Retort Pouch Water Extracts,'' which is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, and may be examined at the Center for Food Safety and

Applied Nutrition's Library, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC 20408.

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Dated: 10/1/98

October 1, 1998

L. Robert Lake
Director
Office of Policy, Planning and Strategic Initiatives
Center for Food Safety and Applied Nutrition

[FR Doc. 98–???? Filed ??–??–98; 8:45 am]

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